



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,333	03/05/2002	Robert B. Dickson	P 0280655	4097
909	7590	11/30/2005	EXAMINER	
PILLSBURY WINTHROP SHAW PITTMAN, LLP			LUCAS, ZACHARIAH	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	

1648

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/936,333	Applicant(s) DICKSON ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 November 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: 15 and 19.
 Claim(s) objected to: _____.
 Claim(s) rejected: 16, 18, 34-36.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
 13. ☐ Other: _____.

Continuation of 5. Applicant's reply has overcome the following rejection(s): The amendment of the specification and the statements regarding the hybridomas M69 and M123 in the Declaration of Biological Deposit submitted on November 8, 2005 have overcome the rejection of claims 15 and 19 under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement.

Continuation of 11. does NOT place the application in condition for allowance because: The Applicant has presented arguments in the After-Final Response of November 8, 2005 in traversal of the rejection of claims 16, 18, and 34-36 for lack of written description for the genus of antibodies which are described as binding with greater affinity to the two-chain form of matriptase than to the single-chain form. The traversal is on the grounds that the disclosure of the M69 and M123 antibodies, and the provision of a screening assay for antibodies with the indicated functional characteristics. The Applicant also notes that for some biomolecules, the identifying characteristics of binding affinity or binding specificity may be sufficient for the identification of the claimed molecule. These arguments are not found persuasive.

With respect to the identification of the M69 and M123 antibodies, while they may be representatives of the claimed genus, they provide no information as to the scope of the genus as a whole. In particular, the identification of these antibodies provides no information as to what other antibodies would be capable performing the same function. The Courts have stated that the presence of multiple species within a claimed genus does not necessarily demonstrate possession of the genus "where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated." See, *In re Smyth*, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973); and *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, at 1405 (Fed Cir 1997)(citing *Smyth* for support). As the disclosure of these antibodies provides no information as to the identification of other antibodies within the claimed genus, other than antibodies that bind to the specific epitopes targeted by these two specific antibodies, their disclosure fails to provide adequate support for the claimed genus.

The Applicant next asserts that they have disclosed a method of producing and screening antibodies which is likely to produce and identify other antibodies according to the claimed genus. However, methods of screening are not sufficient to demonstrate possession (therefore descriptive support) for a claimed genus. See e.g., *University of Rochester v. G.D. Searle & Co.*, 69 U.S.P.Q. 2d 1886, at 1895 (CAFC 2004)(stating that the identification of a screening assay for the identification of a biomolecule is not the same as disclosing the specific biomolecule, and that it is the identification of the specific biomolecules which is required). See also, MPEP § 2163 II.A.2(a). Thus, the Applicant's assertion that they have provided a screening assay is also not found persuasive.

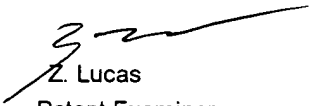
Finally, while the disclosure of an antigen is sufficient to provide descriptive support for an antibody (or genus of antibodies binding that antigen), the antigen must be "fully characterized by its structure, formula, chemical name, physical properties, or deposit in a public depository." MPEP § 2163 II.A.2(a). In the present case, claimed antibodies are not merely any antibodies that target the two-chain form of matriptase, but are antibodies that have a greater binding affinity for this antigen than for the single chain form of the protein. Thus, the claims are directed to antibodies with specificity for specific epitopes (linear or conformational) that give the antibody specificity for one form of matriptase over the other. As there is no description of any such epitopes (other than through the identification of the M69 and M123 antibodies), or any identification of structural or linear regions of the matriptase protein that are specific to, or exposed in, the two-chain form of the protein, the antigens to which the claimed antibodies bind cannot be said to have been "fully characterized."


For each of these reasons, and for the reasons of record, the Applicant's argument in traversal of the written description rejection of claim 16, 18, and 34-36 is not found persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
11/28/05